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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Henry J. WINDLE et al.

Group Art Unit: 1645

Serial No.: 10/068,870

Examiner: Unassigned

Filed: February 11, 2002

For: CLOSTRIDIUM DIFFICILE VACCINE

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Commissioner of Patents
Washington, DC 20231

Sir:

As a means of complying with the duty of disclosure under 37 CFR §1.56, and in accordance with 37 CFR §§1.97 and 1.98, Applicant(s), through the undersigned attorney, submits this Information Disclosure Statement. The patents, publications or other information submitted herewith are listed on the attached Form PTO-1449 and copies are attached.

In accordance with 37 CFR §1.97(b)(1) or (2), this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, or within three months of the date of entry into the national stage of the

above-identified application as set forth in 37 CFR §1.491.
Accordingly, no fee is required.

Respectfully submitted,

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By:

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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P67635US0 GROUP ART UNIT: 1645
 SERIAL NO.: 10/068,870 FILING DATE: February 11, 2002
 APPLICANT(S): Henry J. WINDLE et al. TODAY'S DATE: May 9, 2002

U.S. PATENT DOCUMENTS

*EXAMINER <u>INITIAL</u>	DOCUMENT <u>NUMBER</u>	DATE	NAME	SUB- <u>CLASS</u>	FILING DATE <u>If Appropriate</u>
AA	_____	_____	_____	_____	_____
AB	_____	_____	_____	_____	_____

FOREIGN PATENT DOCUMENTS

DOCUMENT <u>NUMBER</u>	DATE	COUNTRY	SUB- <u>CLASS</u>	TRANSLATION <u>YES</u> <u>(NO)</u>
AC	_____	_____	_____	_____
AD	_____	_____	_____	+

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

- ✓ AE Emanuela CALABI et al., "Molecular Characterization of the Surface Layer Proteins from Clostridium difficile", Mol. Microbiol., (2001), Vol. 40, pages 1187-1199.
- ✓ AF Marina CERQUETTI et al., "Characterization of Surface Layer Proteins from Different Clostridium difficile Clinical Isolates", Microbial Pathogenesis, (2000), Vol. 28, pages 363-372.
- ✓ AG S.H. CHENG et al., "Clostridium difficile-Associated Diseases: Comparison of Symptomatic Infection Versus Carriage on the Basis of Risk Factors, Toxin Production, and Genotyping Results", Clin. Infect. Dis., (1997), Vol. 25, pages 157-158.
- ✓ AH Michel DELMEE et al., "Comparison of Serogrouping and Polyacrylamide Gel Electrophoresis for Typing Clostridium difficile", J. Clin. Microbiol, (1986), Vol. 24, No. 6, pages 991-994.

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- AI ✓ Michel DELMEE et al., "Characterization of Flagella of Clostridium Difficile and Their Role in Serogrouping Reactions", Journal of Clinical Microbiology, (1990), Vol. 28, No. 10, pages 2210-2214.
- AK ✓ Tuomo KARJALAINEN et al., "Molecular and Genomic Analysis of Genes Encoding Surface-Anchored Proteins from Clostridium Difficile", Infection and Immunity, (2001), Vol. 69, No. 5, pages 3442-3446.
- AL ✓ C.P. Kelly, et al., "Clostridium Difficile Colitis", New England Journal of Medicine, (1994), Vol. 330, No. 4, pages 257-262.
- AM ✓ Lorraine KYNE et al., "Asymptomatic Carriage of Clostridium Difficile and Serum Levels of IgG Antibody Against Toxin A", The New England Journal of Medicine, (2000), Vol. 342, No. 6, pages 390-396.
- AN ✓ Donald Y. M. LEUNG et al., "Treatment with Intravenously Administered Gamma Globulin of Chronic Relapsing Colitis Induced by Clostridium Difficile Toxin", J. Pediatr., (1991), pages 633-637.
- AO ✓ Lynne V. MCFARLAND et al., "Correlation of Immunoblot Type, Enterotoxin Production, and Cytotoxin Production with Clinical Manifestations of Clostridium Difficile Infection in a Cohort of Hospitalized Patients", Infection and Immunity, (1991), Vol. 59, No. 7, pages 2456-2462.
- AP ✓ Maury Ellis MULLIGAN et al., "Elevated Levels of Serum Immunoglobulins in Asymptomatic Carriers of Clostridium Difficile", Clin Infect. Dis., (1993), 16(Suppl 4), pages S239-244.

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- AQ / Henrik NIELSEN et al., "Identification of Prokaryotic and Eukaryotic Signal Peptides and Prediction of their Cleavage Sites", Protein Engineering, (1997), Vol. 10, No. 1, pages 1-6.
 AR / G.L. O'NEILL et al., "Modification of a PCR Ribotyping Method for Application as a Routine Typing Scheme for Clostridium difficile", Anaerobe, (1996), Vol. 2, pages 205-209.
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 AT / D.H. PERLMUTTER et al., "Chronic Diarrhea Associated with Hypogammaglobulinemia and Enteropathy in Infants and Children", Digestive Diseases and Sciences, (1985), Vol. 30, No. 12, pages 1149-1155.
 AU / Ian R. POXTON et al., "Variation in the Cell Surface Proteins of Clostridium difficile", Anaerobe, (1999), Vol. 5, pages 213-215.
 AV / Janet K. SHIM et al., "Primary Symptomless Colonisation by Clostridium difficile and Decreased Risk of Subsequent Diarrhoea", The Lancet, (1998), Vol. 351, pages 633-636.
 AW / U.B. SLEYTR et al., "Crystalline Bacterial Cell Surface Layers", Molecular Microbiology, (1993), Vol. 10, No. 5, pages 911-916.

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